James W. Stitley, Research Biochemist
785 S. Wandering River Rd.
Cornville, Arizona 86325
March 27, 2014

White Paper on Smart Meter Safety Concerns

Credentials:

I have been a Research Biochemist for more than 48 years in a variety of industries as well as a Consultant in developing and/or implementing advanced technologies. Most have involved animal and human test models for efficacy and safety, with the latter being the greater FDA concern. In a meeting many years ago with the FDA in Washington, they said its all about "Safety, Safety, Safety". These studies were ALWAYS done during the development phase BUT BEFORE any rollout or implementation. In 1987 and 1988 I put on two International Conferences on "Sensors and Control Systems" and the second on "Applications of Sensor and Control Technology". ***See Expanded Resume for history and Major Accomplishments.*** I have worked for, or with the FDA, USDA, EPA, CRO's, NASA, Universities, private companies and Regulatory Legal Firms and provided Expert Testimony in local, state and national hearings. Expert in Fine Particle Analysis and Inhalation Toxicology. My industry experience includes the food industry, pharmaceutical, nutraceutical and OTC product safety; established the first commercial U.S.food testing lab following the first FDA Food Labeling Regulations and later FDA studies on all means of fine particle inhalation. Consulted in Technology Transfer between unrelated industries and ran several international Consortia. Developed, Published and Replaced an incorrect EPA prediction model that would have cost companies in the San Francisco Bay Area about $1 million per line in a plant, often with multiple production lines.

Potential Risks of Implementation of Smart Meters Before Full Safety Clearance:

In recent years I have been working in brain research and have had a professional concern for the issue of Smart Meter deployment in the ABSENCE of full and comprehensive Safety Studies as is required by the Food and Drug Administration (FDA) as they DO regulate all medical devices for efficacy, safety, power sources and anything that might interfere with their biological functions. In the Code of the Federal Register (CFR) and the FDA Guidelines, smart meters are too new to show up yet on the watch list. But with widespread implementation in the absence of full safety studies, it is only a matter of time. **The FDA has ALWAYS placed the proof of efficacy AND Safety squarely on the shoulders of manufacturers**, whether ingredients, finished products or even medical devices. They are also quick to act in putting Product Recalls into place as soon as a negative variant is identified. These are very expensive and creates a lot of bad press with the public and other Regulatory Agencies.

: In recent years, the greatest breakthroughs have been in Biomedical Engineering from Gene regulation to body organs, metabolism and brain functions. Many of these newest discovers involve implantation of sensors and control systems right into the body or brain. Most operate on small and subtle electrical signals, and many are life sparing devices. The risk of implementing Smart Meters BEFORE **extensive** proven safety studies are external electrical interferences. One example is many of the newer Pacemakers also now having permanent defibrillator sensor wires imbedded into the heart (I have a male relative with one of these and he is restricted where he can and cannot go to prevent any possible electrical interferences). There are cochlear implants for hearing and sensors for control of seizures right into the brain. There are many other examples where these advanced life sparing implanted devices might be prone to interferences from higher, external direct, continuous or pulsing energies. What is an acceptable risk from any external electrical interferences on such patients in the absence of full proven safety?

In the pharmaceutical industrial there are well designed FDA required paths to proof of safety, from in vitro cellular to in vivo small to progressively larger animals, primates and human where possible, like Functional MRI Brain Scans. In today's newest biomedical engineering sensors and implants, this horizon has expanded rapidly.

Currently I have not been able to find any safety studies on continuous or pulsed electrical impulses for Digital OR FULL Smart Meters as to strength, distance, fetal development, pregnant women; children and early in vivo and post delivery brain development, adult, elderly, many with medical implants, e.g. insulin pumps for precise delivery amounts and timing.

U.S. Food and Drug Administration (FDA)

What do Smart Meters have to do with the FDA? Upon a first look, NOTHING. Upon a second look, EVERYTHING.

The FDA is responsible for all aspects of Medical Devices of all types. Initially this category did not fall under food and drug regulations, but as oversight of the safety of these devices became critical, it was added to its responsibilities, and is today its own category on the FDA website. In this regard, the FDA is also responsible for any interfering external electrical interferences, that might result in an injury or death of patients requiring these devices. Currently on the **FDA website** there are **1830** Search Results for external electrical or wireless interferences, interruptions, or failure of various medical devices from wheel chairs to implanted sensors. See www.fda.gov/medicaldevices/ and www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments

There is also a 8-page "**Medical Devices and EMI: The FDA Perspective**" report on this website – a great overview of its concerns for any type of EMI interferences , Don Witters, Center for Devices and Radiological Health, FDA, Rockville, MD 20850. The FDA has always held it is the responsibility of manufacturers of all type to understand

and properly design test protocols for full safety **BEFORE** released into the public sector.

February 14, 2014, Dr. Ralf Zimmerman, MD, a highly regarded Medical Doctor – and Principle Investigatory at Columbia University Medical Center received a 6-page Warning Letter on faulty experimental design protocol and supervision, including …'the protection of human subjects'. The FDA cites the associated Code of Federal Register (CFR) sections of malcompliances, in the **Warning Letters** section of the FDA website. **In 2013 the FDA issued 483 Warning Letters of various types.** They typically require a very rapid response to the letter outlining corrective action. These letters can also be followed with significant financial or other penalties for failure to comply.

Peering into the future, **IF** the FDA begins to see increasing problems of public health and safety as a result of the many scientific studies and data already collected from these types of EMF devices, I could see the FDA adding another related category to the FDA's Oversight Responsibilities, likely via congressional action, to cover Smart Meters much like was done with Medical Devices several years ago.

The FDA could be an ally to us in assuring full safety studies before rollouts, or reversing those already in place. I believe with what is seen thus far in the many scientific studies, there is sufficient evidence of risk to public health and safety to interest the FDA and ask them to start tracking these studies. The rationale is the interferences with medical devices, sensors, implants, etc. already monitored. In addition, the direct safety observations and measurements and data as it relates to direct effects on pregnant women, fetal development, adults, children, the elderly – short and long term. There are plenty of examples in after the fact attempts at correction/regulation for the large number of Multiple Sclerosis patients, of both genders in Utah from 'down winders' nuclear testing, asbestos exposure, early bladder cancers from first generation artificial sweeteners, smoking and cancer and many more. We cannot afford to wait 10 years or more to see any manifestations of disease states resulting from the types of exposure from Smart Meters and their respective networked grids.

We are asking for is a consideration of a proactive review of these potential direct, and indirect, effects of documented studies on Smart Meters to date, and other studies still needing to be done to assure FULL safety of these devices and the grid they are integral to, and the 24/7 non-voluntary exposure to all segments of human (and animal) populations.

Possible Long Term Risks if no Moratorium Before Proven Safe

The public has been asking if major funds are being set aside for any 'after the fact' damages to any sector of the population harmed in any way after chronic use of Smart Meters? These would be similar to injuries from tobacco, lead in paint, bladder cancer for early sweeteners, asbestos, and **many others**. I understand the tobacco cancer fund is still more than $100 million for late developing lung cancer damages.

In Sedona or all of Arizona, who will establish this **remedy fund** for long term damages? – the City of Sedona? Arizona Corporation Commission overseeing APS? APS itself? The State of Arizona?

This will be the first technology I know of exposing **every person to involuntary 24/7** electrical continuous or pulsed radiation within a networked grid system without PROVEN Safety studies to meet FDA Guidelines in experimental design, protocols, acute and chronic exposure for ALL sectors of human population? It may not happen but without a Moratorium on installing and implementation first, we cannot guess what will happen in 5, 10 or 20 years or more down the road. The human and financial costs could be staggering.

WHY the rush to implement BEFORE proven safe by FDA standards, not a meta analysis literature search??? ACTUAL studies must be done. My last company spent $250 million dollars over 15 years on a simple amino acid for slowing or preventing Alzheimer's Disease or Age Associated Memory Impairment (AAMI) using the most advanced and sophisticated scientific studies including 1000 people from two countries getting Functional MRI's, and many dozens of other tests/studies for complete biological safety. This product was sold worldwide except for the United States, and there we NO safety issues per the FDA. FDA mentions the Thalidomide crisis that was avoided in the U.S., unlike other countries who rolled out that new drug.

And finally, the Heart, Brain, Nervous System and Cellular Communication are our own "medical devices" we **ALL** carry inside us and are vulnerable to any external electrical interference.

Suggested Action Steps:

An **IMMEDIATE Moratorium** would buy time for ALL the Stake Holders to discuss options, assess the risks in carefully designed short and long term exposure studies. These studies are very costly and time consuming, but the consequences would be even greater!

Much to consider and weigh. Nothing may happen, but "what if" down the road . . . ? We would have no defensible position with the FDA should significant health risks arise, in anyone, especially users of medical devices or sensor complications if they ask to see what safety studies as an industry we did first to PROVE complete safety? There is NO "User Group" for Smart Meter exposure or avoidance in a Smart Grid network!

The FDA could determine the manufacturers of the meters themselves are responsible for proven safety and sufficient internal systems to reduce environmental "electrical contamination". Often the FDA follows up the line responsibility to assure oversight in safety – what is known, what needs to be done, hire expert medical investigators, develop an acceptable experimental protocol for actual biological effects and publish the results. In some states like California, there is a law for Shared Negligence of umbrella liability. I know of a case where despite a company placing all the safeguards in place, when the consumer was responsible for near fatal outcome, both shared negligence in Settlement.